IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER, PH.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to exclude the opinions and testimony of Scott A. Guelcher, Ph.D. The cases to which this motion applies are identified in Ex. A to this motion.

In this case, Dr. Guelcher seeks to opine that the Prolene in Ethicon mesh products[1] oxidizes and degrades *in vivo*. His testimony should be excluded because it does not meet the requirements of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591-95 (1993). *Daubert* requires a court to consider whether a scientific theory has been tested, whether it is subject to peer review, whether it is subject to a known rate of error, and whether it is generally accepted in the scientific community. *See Oglesby v. Gen. Motors Corp*., 190 F.3d 244, 249 (4th Cir. 1999); *Eghnayem v. Boston Sci. Corp*., 57 F. Supp. 3d 658 (S.D. W. Va. 2014) (testing failed to meet peer-reviewed standards).

[1] Dr. Guelcher's expert report pertains to "devices manufactured by Ethicon to treat Stress Urinary Incontinence (SUI) and pelvic organ prolapse (POP)." This Motion refers to these products collectively as "Ethicon mesh products."

Application of the *Daubert* criteria to Dr. Guelcher's opinions demonstrates that the Court should preclude him from testifying in this case. Dr. Guelcher's hypothesis is unsupported by testing, scientific literature, and the scientific community. Nor can Dr. Guelcher explain when any alleged oxidation or degradation will be triggered.

Furthermore, Dr. Guelcher's opinions are unreliable because the testing he conducted with Dr. Russell Dunn—which formed the basis for Dr. Guelcher's opinion that Prolene is subject to oxidation—was found by this Court to be scientifically unsound. *Mathison v. Boston Sci. Corp*., No. 2:13-cv-05851, 2015 WL 2124991, at *22 (S.D. W. Va. May 6, 2015) (excluding opinion of Dr. Dunn because his testing with Dr. Guelcher failed to follow a written protocol or use a sufficient sample size). In *Mathison*, this Court excluded Dr. Guelcher's testimony because it depended on unreliable testing he conducted with Dr. Dunn. *Id.* at *23.

Now, in the face of the Court's ruling, Dr. Guelcher simply says that he no longer relies on that unreliable testing. But, as in *Mathison*, Dr. Guelcher's testimony means nothing without the testing. He has no testing, no peer-reviewed literature of testing conducted on Prolene, no general acceptance that Prolene oxidizes or degrades—much less in a clinically significant way—and he cannot say how any alleged oxidation or degradation takes place.

Dr. Guelcher's refusal to rely on his own testing of the central premise of his opinions—*i.e.*, that Prolene is susceptible to oxidation—renders his opinion unreliable and inadmissible. For this, and other reasons, the Court should exclude his entire testimony.

FACTUAL STATEMENT

Dr. Guelcher is Plaintiffs' expert witness on the alleged *in vivo* chemical oxidation and degradation of the Prolene used in Ethicon mesh products. Dr. Guelcher's central opinion is that chemicals present in the human body—namely, reactive oxidative species ("ROS")—react with

and deplete the antioxidants used in the Prolene from which Ethicon mesh products are made, causing the Prolene to oxidize and degrade over time. *See* Ex. B, Expert Report of Scott A. Guelcher, Ph.D. ("Guelcher Report") at 3.

Although Dr. Guelcher cannot determine the time at which Prolene mesh will degrade, he opines that it will degrade at some undefined point. *See* Ex. C, Guelcher 12/18/14 Dep. Tr. 45:18–46:1. (testifying that degradation is "unpredictable"); *Id*. at 47:11–18 (testifying that he "just can't answer" the question of what the earliest time Prolene can degrade is); *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 95:18–96:3 (opining that he "would expect [the Ethicon mesh products at issue] to oxidize and degrade," although "the timing of that is unpredictable"). Dr. Guelcher uses this opinion as a basis for offering opinions regarding numerous complications, as well as alleged device malfunction and failure. *See* Ex. B, Guelcher Report at 3.

Dr. Guelcher previously offered his degradation opinions at trial in *Huskey v. Ethicon, Inc.*[2] Although the Court questioned before trial whether there was evidence that Prolene is distinct from other forms of polypropylene, *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014), Dr. Guelcher acknowledged at trial that Prolene is different from other forms of polypropylene because it contains proprietary antioxidants. Specifically, Dr. Guelcher testified as follows:

> Q. And what makes Prolene Prolene as opposed to simple polypropylene are the additives that you talked about, correct?
>
> A. Yes. The brand name Prolene is defined by the additives that are added to the polypropylene."
>
> . . . .

[2] This Court permitted Dr. Guelcher to opine on general causation and the alleged oxidative degradation of Prolene. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D. W. Va. 2014).

> Q. And those additives are what makes Prolene different from the other polypropylene medical devices on the market, correct?
>
> A. . . . Yes.

Ex.E, *Huskey* 8/25/2014 Trial Tr. at 156:14–18; 157:11–17; *see also* Ex. D, Guelcher 3/23/16 Dep. Tr. 87:23-88:9.

Dr. Guelcher also conceded at trial that tests have shown that antioxidants retard degradation in polypropylene. *See* Ex. E, *Huskey* 8/25/14 Trial Tr. 175:14–16 (antioxidants extend life of polypropylene); *id.* at 176:8-21 (degradation observable in 90 days did not occur in polypropylene treated with antioxidants); *see also* Ex. F, J. Blavias, *et al.*, *Safety Considerations for Synthetic Sling Surgery*, 18 Nat. Rev. Urology 17 (2015) (question of degradation "unresolved" but antioxidants retarded degradation in five-month test).

Dr. Guelcher admitted that he had never conducted any tests on Prolene sutures or Prolene mesh. *See* Ex. E, *Huskey* 8/25/14 Trial Tr. 170:19–171:4. Moreover, he could not identify any peer-reviewed study showing that Prolene loses its antioxidants:

> Q. And in the 50 years that Prolene polypropylene has been used for implantation in humans, you're not aware of any peer-reviewed study which suggests that Ethicon Prolene loses its antioxidant package such that it oxidizes and becomes embrittled, are you?
>
> A. I've not seen that in a peer-reviewed study.

Id. at 178:6–11.[3]

Recognizing these failings, Dr. Guelcher subsequently collaborated with Dr. Dunn[4] to test Prolene in an effort to prove that it is susceptible to oxidation. *See* Ex. E, *Huskey* 8/25/14

[3] Dr. Guelcher's concession is consistent with the testimony of defense materials experts, who explain that the antioxidants in Prolene resist degradation. *See, e.g.*, Ex. G, MacLean 9/29/15 Dep. Tr. 106:10–107:4 (explaining that Prolene is significantly different from polypropylene); *id.* at 124:3–23 (testifying that the antioxidants in Prolene work); *id*. at 152:13–20 (explaining that antioxidants negate the potential for degradation); *id.* at 389:1–4 (stating that he has not seen any evidence that Prolene mesh degrades in the body over the lifetime of the patient).

Trial Tr. 179:23 ("in the process" of testing as of Aug. 25, 2014); *see* Ex. C, Guelcher 12/18/14 Dep. Tr. 107:24–108:12 (explaining that his test is an attempt to respond to Ethicon's arguments in *Huskey* that "we could not say definitively that Prolene polypropylene oxidizes").

To that end, Drs. Guelcher and Dunn exposed pieces of mesh cut from a single TVT exemplar and a pellet of generic polypropylene without antioxidants to a solution of cobalt chloride and hydrogen peroxide, which allegedly mimics conditions inside the human body experiencing a foreign body reaction. *See* Ex. H, PCT *In Vitro* Study Protocol at 209–210**;** *see also* Ex. C, Guelcher 12/18/14 Dep. Tr. 28:4–18; 102:16–105:4; 106:16–107:23. They allegedly exposed the Prolene to these chemicals for up to six weeks, conducting weekly analytical chemistry evaluations using FTIR, SEM, and XPS. *See* PCT *In Vitro* Study Protocol. According to Dr. Guelcher, their testing showed that "Prolene polypropylene used to manufacture the TVT device can oxidize and degrade under oxidative conditions similar to those experienced in the human body after implantation." *Id.* at 123:25–124:8.

That Dr. Guelcher perceived this testing as significant to his degradation opinion is evident in his efforts to publicize and rely on it both in and out of litigation. For instance, Dr. Guelcher first informed Ethicon that he sought to base his degradation opinions on the results of this testing at his deposition in *Perry v. Ethicon, Inc.*, a case filed in California state court. *Id.* at 100:23-101:23. He subsequently sought to rely on the testing in a similar case against another manufacturer. *See* Ex. I, Rule 26 Expert Report of Scott A. Guelcher, Ph.D. at 16–18, *Winebarger v. Boston Sci. Corp.*, No. 2:13-cv-28892 (Doc. No. 48-1) (S.D. W. Va. Jan. 16, 2015) (explaining same testing conducted on Boston Scientific meshes) ("*Winebarger* Report").

[4] Plaintiffs designated Dr. Dunn as an expert in *Huskey*. By order entered July 8, 2014, the Court limited the opinions of Dr. Dunn, and Dr. Dunn did not testify at the *Huskey* trial.

Dr. Guelcher also delivered presentations based on his testing, including at a meeting of the American Institute of Chemical Engineers in November 2014, *see* Ex. C, Guelcher 12/18/14 Dep. Tr. 249:7–250:21, and at a meeting of the International Urogynecological Association in June 2015, *see* Ex. J, Guelcher 9/15/15 Dep. Tr. 20:13–16; 30:2–32:11.[5]

In addition, Dr. Guelcher worked with Dr. Dunn on an abstract based on their testing in which they conclude that the "[o]xidative degradation of PP pelvic mesh was evidenced by chemical and physical changes under simulated *in vivo* conditions." *Id.* at 30:2–11; *see also* Ex. K, S.A. Guelcher & R.F. Dunn, "Oxidative Degradation of Polypropylene Pelvic Mesh *In Vitro*," 26 (Supp. 1) Int'l Urogynecology J. 55, 56 (2015) ("Guelcher Abstract").[6]

Plaintiffs subsequently identified Dr. Guelcher as an expert in *Mullins v. Ethicon*. Notably, however, Dr. Guelcher did not include the testing in his August 2015 Report or on his reliance list in that case. As the timing and method of Dr. Guelcher's production of the testing information to Ethicon in *Perry* prevented a meaningful examination,[7] Ethicon notified Plaintiffs and Dr. Guelcher that he would be examined on this testing at his deposition for that case. *See* Ex. M, Notice of Deposition of Dr. Scott A. Guelcher (Sept. 4, 2015).

Although Ethicon presented Dr. Guelcher with the raw data and test results upon which he based his presentation to the IUGA and his published abstract, and on which he sought to base

[5] Dr. Guelcher participated in a mock trial at the IUGA meeting, during which he testified about the findings he presented at the IUGA meeting, and was subject to cross-examination by counsel for plaintiffs in pelvic mesh litigation. *Id.* at 20:15–22:6; 24:13–22.

[6] Neither Dr. Guelcher nor Dr. Dunn disclosed in the article that they were paid experts for plaintiffs in pelvic mesh litigation. *See* Ex. K, Guelcher Abstract at 56; *see also* Ex. J, Guelcher 9/15/15 Dep. Tr. 110:20–112:17.

[7] For this reason, plaintiffs in *Perry* declined to offer Dr. Guelcher's testimony on the testing. *See* Ex. L, *Perry* 2/3/15 Trial Tr. 2561:4–23.

his opinion in *Perry* and *Winebarger*, Dr. Guelcher repeatedly refused to rely on—or even answer questions about—the testing. *See, e.g.*, Ex. J, Guelcher 9/15/15 Dep. Tr. 60:21–25; 81:16–82:4; 82:23–83:10; 116:9–11.[8]

Plaintiffs again disclosed Dr. Guelcher as an expert in this litigation. He testified that his opinions have not changed since he was deposed in *Mullins*, and that he has conducted no testing since that time. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 21:18-20; 22:7-17. Significantly, Dr. Guelcher continues to refuse to rely on the testing that is central to his opinions. *Id.* at 35:17-20.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3, (S.D. W. Va. July 8, 2014).

II. The Court Should Exclude Dr. Guelcher's Degradation Opinions As Unreliable.

A. Dr. Guelcher refuses to rely on his own testing that purportedly supports his opinions.

In this case, Dr. Guelcher's central opinion—that Prolene is subject to oxidation and degradation—is not only subject to testing, but Dr. Guelcher has already completed a test of Prolene in collaboration with Dr. Dunn designed to answer this very question. *See, e.g.*, Ex. C, Guelcher 12/18/14 Dep. Tr. 102:16–105:4; 106:16–107:23.

Yet, when confronted about the testing at deposition, Dr. Guelcher has repeatedly refused to rely on it for his opinions. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 35:17–20; *see also* Ex. J, Guelcher 9/15/15 Dep. Tr. 60:21–25; 81:16–82:4; 82:23–83:10; 116:9–11. Indeed, although this

[8] Notably, Dr. Vladimir Iakovlev, an expert for Plaintiffs in this case, also refused to rely on the Dr. Guelcher's testing. *See* Ex. N, Iakovlev 9/14/15 Dep. Tr. 37:25–38:17. Dr. Iakovlev's opinions are the subject of a companion motion, and should also be excluded from this case.

testing speaks to the core of his degradation opinions, he testified that he was "not prepared" to address the testing at deposition. *Id.* at 83:12-20. When pressed to explain his refusal to rely on his testing, Dr. Guelcher has represented to counsel for Ethicon that he is "not relying on it because we haven't published it." *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 35:17-36:11; *see also* Ex. J, Guelcher 9/15/15 Dep. Tr. 106:3-10 (same).[9]

Given that Dr. Guelcher previously tried to rely on this testing both in and out of court, his rationale for refusing to rely on the testing in this case rings hollow. *See* Ex. C, Guelcher 12/18/14 Dep. Tr. 100:23-101:23; *see also* Ex. I, *Winebarger* Report at 16-18. Furthermore, Dr. Guelcher's refusal to rely on his own testing to support his opinions, coupled with his obfuscation regarding the testing, prove the lack of reliability in his opinions.[10]

Dr. Guelcher's refusal to rely on his testing is particularly striking in this case, because experts for Ethicon have demonstrated that Dr. Guelcher's methodology is fundamentally flawed. Specifically, Dr. Shelby Thames examined the raw data on which Dr. Guelcher relied and found no evidence of oxidative degradation. *See* Ex. O, Expert Report of Shelby F. Thames, Ph.D. at 69-71. Similarly, testing conducted by Dr. Steven MacLean—pursuant to the same treatment protocol used by Drs. Guelcher and Dunn—revealed no evidence of any degradation on the Prolene samples. *See* Ex. P, Expert Report of Steven B. MacLean, Ph.D. at 54–56. The Court's decision to exclude the testing Dr. Guelcher conducted with Dr. Dunn was thus vindicated.

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[9] Notably, Dr. Guelcher recently testified that he and Dr. Dunn still "don't know what we're going to do with it yet," and that he cannot remember the last time they discussed publication of the testing. *See* Ex.D, Guelcher 3/23/2016 Dep. Tr. 37:13–19.

[10] Indeed, Dr. Guelcher seeks to distance himself from the testing by claiming that he "can't remember" relying on it in *Perry* and does not even "recall the [*Winebarger*] litigation." *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 30:19–31:21.

B. The scientific literature on which Dr. Guelcher relies does not support his degradation opinions because it is either not about Prolene or concerns sutures whose degradation, if any, has not been shown to cause clinical harm.

As Dr. Guelcher recognized after the *Huskey* trial, his testing was the lynchpin to his degradation opinions. *See* Ex. C, Guelcher 12/18/14 Dep. Tr. 107:24–108:12. Without that testing, he has no evidence that Prolene is subject to oxidative degradation *in vitro*, much less *in vivo*, because the scientific literature does not support his theories.

Dr. Guelcher's own testimony demonstrates that many of his opinions are not supported by scientific literature. For example, Dr. Guelcher admitted at trial that he cannot identify a single peer-reviewed study suggesting that Prolene loses its antioxidant package such that it oxidizes and degrades. *See* Ex. E, *Huskey* 8/25/14 Trial Tr. 178:6–11. He conceded at deposition that he cannot point to a single study showing that chain scission—a prerequisite for degradation—occurs *in vivo* in Prolene. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 66:11–17.

Dr. Guelcher likewise admitted that there is no scientific evidence that Ethicon mesh products become embrittled; rather, it is merely something he "believe[s]." *See id.* at 72:11–73:23; *see also id.* at 75:1–11 ("Q. Nor are you aware of any evidence that any of those nine products, specific products, have become embrittled *in vivo*, are you? . . . A. Again, I've not seen anybody actually measure that . . . . Q. And you haven't measured that, have you? A. No.").

In addition, Dr. Guelcher acknowledged that "no one has shown—published that [the Ethicon mesh products at issue] lose molecular weight" *in vivo*. *Id.* at 75:12–18. He also testified that he is unaware of any study or data confirming that Ethicon mesh products degrade such that their intended function is compromised during a patient's lifetime. *Id.* at 104:22–105:7.

Furthermore, even where Dr. Guelcher cites to scientific literature, scrutiny of the studies reveals that they do not actually support his opinions. For this reason, and because he has no

testing on which he can rely to support his opinion that Prolene mesh degrades *in vitro*, all of his opinions in this case must be excluded.

a. Dr. Guelcher's bases his opinions on a logical fallacy.

Having admitted that Prolene is different than other forms of polypropylene, *see, e.g.*, Ex. D, Guelcher 3/23/16 Dep. Tr. 87:23–88:9, Dr. Guelcher now seeks to base his degradation opinions on three studies that, "taken together," purportedly demonstrate that Ethicon mesh products are subject to *in vivo* oxidative degradation. *See* Ex. B, Guelcher Report at 8-10; Ex. Q, P. Moalli, *et al.*, *Characterization of the Host Inflammatory Response Following Implantation of Prolapse Mesh in Rhesus Macaque*, 213(5) Am. J. Obstet. Gynecol. 668.e1-668e10 (Nov. 2015); Ex. R, V. Iakovlev, *et al.*, *Degradation of Polypropylene* In Vivo: *A Microscopic Analysis of Meshes Explanted From Patients*, J. Biomed. Mater. Res. Part B (2015); Ex. S, A. Imel, *et al.*, In Vivo *Oxidative Degradation of Polypropylene Pelvic Mesh*, 73 Biomaterials 131–41 (2015). Yet, scrutiny of these studies reveals that Dr. Guelcher has presented nothing more than a bait-and-switch.

First, Dr. Guelcher relies on the Moalli study to show that Ethicon mesh products elicit the foreign body reaction *in vivo*. *See* Ex. B, Guelcher Report at 9. But while the Moalli study incorporated Prolene mesh in its data set, Dr. Guelcher admitted that the study made no findings as to oxidation, much less degradation. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 59:10–19.

Next, Dr. Guelcher points to a study he co-authored with Dr. Iakovlev in 2015 to establish the presence of inflammatory cells and oxidative enzymes on or near the surface of "PP fibers." *See* Ex. B, Guelcher Report at 9. Tellingly, however, neither Dr. Guelcher's discussion

of the study, nor the image he reproduced from it, actually address Prolene. *See id.* at 9 & 10 fig. 7.[11]

Finally, Dr. Guelcher seeks to link Prolene meshes to oxidative degradation by relying on the Imel study, which Dr. Guelcher states "confirmed that the foreign body reaction to implanted PP mesh results in oxidative degradation of the mesh." *See* Ex. B, Guelcher Report at 9. But, as Dr. Guelcher admitted at deposition, the Imel study did not address Prolene. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 134:5–11.

Despite Dr. Guelcher's attempt at misdirection, these studies do not establish that Ethicon mesh products are subject to oxidative degradation *in vivo*. The Court should not permit him to circumvent sound scientific principles by selectively "take[ing] together" a hodgepodge of studies—unrelated in terms of materials, methods, endpoints, or findings—as proof of a proposition that none of them examined.

b. Dr. Guelcher's relies on studies that do not assess Prolene.

Cannot confirm either oxidation or Prolene. Dr. Guelcher relies on a 2010 study by Clave to support his opinion that Prolene is subject to oxidative degradation. *See* Ex. B, Guelcher Report at 17. But Dr. Guelcher admitted at trial that Clave's study, encompassing 100 meshes from multiple manufacturers, expressly states that while there are many "hypotheses concerning the degradation of the PP . . . [n]one of these, particularly direct oxidation, could be confirmed in this study." *See* Ex. E, *Huskey* 8/25/14 Trial Tr. 184:11–185:12; *see also* Ex. T, A. Clave, *et al.*, *Polypropylene As A Reinforcement In Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants*, 21 Int. Urogynecol. J. 261, 266 (2010).

[11] In addition, this study is based on the unreliable methods employed by Dr. Iakovlev, whose degradation hypothesis has been disproven. *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, Mem. in Supp. of Mot. to Exclude Dr. Iakovlev, at 6-7.

Not Prolene and Not Pelvic Mesh. Dr. Guelcher relies on a study by Wood to support his oxidative degradation opinions. *See* Ex. B, Guelcher Report at 17; *see also* Ex. U, A.J. Wood, *et al., Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient*, 24 J. Mater. Sci. Mater. Med. 1113 (2013). Dr. Guelcher has acknowledged at trial, however, that the study addresses hernia meshes, not meshes used in the pelvic floor. *See* Ex. E, *Huskey* 8/25/2014 Trial Tr. 183:20–21. He also admitted that nothing in the Wood study suggests that it analyzed Prolene. *Id.* at 183:22–23.

Notably, the Wood study's finding that oxidized polypropylene has an FTIR signature of 1740 cm^{-1} stands in stark contrast to the Dr. Guelcher's test results for TVT. *See* Ex. O, Thames Report at 69 ("Dr. Guelcher reports oxidation of the un-stabilized PP sample evidenced by the peak at 1736 cm^{-1}. However, no such peak is present in the TVT sample subjected to the same oxidation medium.").

Not Prolene and Speculative. Dr. Guelcher states that Costello found that polypropylene meshes are subject to oxidative degradation and device failure based on "comparisons made between pristine and explanted samples via molecular weight, SEM imaging, and compliance testing." *See* Ex. B, Guelcher Report at 17. Dr. Guelcher's assertion is simply incorrect—neither of the Costello articles cited by Dr. Guelcher report the molecular weight of either pristine or explanted material. *See* Ex. V, C.R. Costello, *et al., Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient*, 14 Surg. Innov. 168 (2007); Ex. W, C.R. Costello, *et al., Materials Characterization of Explanted Hernia Meshes*, 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007). Moreover, while the SEM photomicrographs presented by Costello show cracking on the surface of fibers, the absence of analysis as to the composition of the cracked layer renders any conclusion speculative.

No Evidence that Prolene becomes Embrittled. Dr. Guelcher relies on a study by Fayolle published in 2000 to support his opinion that polypropylene is subject to embrittlement due to oxidative degradation, and he even incorporates into his expert report charts used in the Fayolle study. *See* Ex. B, Guelcher Report at 6–7; *see also* Ex. X, B. Fayolle, *et al.*, *Oxidation Induced Embrittlement in Polypropylene—A Tensile Testing Study*, 70 Polymer Degradation & Stability 333 (2000). But Dr. Guelcher has admitted that the Fayolle study did not address polypropylene treated with antioxidants, like Prolene. *See* Ex. Y, Guelcher 3/25/14 Dep. Tr. 93:6–94:11.

Dr. Guelcher has also admitted that he was not aware of *any* study of polypropylene treated with antioxidants (like Prolene) that would support his opinions regarding embrittlement. *Id.* at 94:6–11; *see also* Ex. D, Guelcher 3/23/16 Dep. Tr. 72:11–73:23. Dr. Guelcher has further admitted that the Prolene antioxidant package makes it unique from other polypropylene mesh. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 87:23–88:9; *see also* Ex. E, *Huskey* 8/25/14 Trial Tr. 156:14–18; 157:11–17. Any conclusions based on this study regarding Prolene (or any polypropylene treated with antioxidants for that matter) are nothing but speculation.

Antioxidants work. Dr. Guelcher relies on a 1976 study by Liebert to support his opinions that polypropylene is subject to oxidative degradation. *See* Ex. B, Guelcher Report at 6–7, 12; *see also* Ex. Z, T. Liebert, *et al.*, *Subcutaneous Implants of PP Filaments*, 10 J. Biomed. Mater. Res. 939 (1976). Dr. Guelcher has previously admitted, however, that the Liebert study actually found that antioxidants are effective at preventing degradation in polypropylene. *See* Ex. Y, Guelcher 3/25/14 Dep. Tr. 73:16–74:1.[12]

[12] Dr. Guelcher opines that "[p]olypropylene reacts with molecular oxygen by autoxidation outside the body at elevated temperatures, resulting in chain scission and deterioration of its mechanical properties." *See* Ex. B, Guelcher Report at 3. At deposition, he admitted that

As the Fourth Circuit explained, the "goal of the *Daubert* analysis is to ensure that 'an expert, whether basing his testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Marsh v. W.R. Grace & Co.*, 80 F. App'x 883, 886 (4th Cir. 2003) (quoting *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). It cannot be said that offering an opinion based solely on studies that do not address the subject matter of the opinion—here, Prolene—is consistent with the "intellectual rigor" employed by biomedical engineers.

Defendants acknowledge that the Court has previously questioned the genuineness of Defendants' position that Prolene has chemical characteristics that make it materially distinct from generic polypropylene. *See Huskey*, 29 F. Supp. 3d at 703. The evidence marshalled above, including Dr. Guelcher's testimony at the *Huskey* trial and in subsequent depositions, (*see supra* at 4–5), proves that antioxidants do make Prolene different. Furthermore, none of the studies on which Dr. Guelcher relies impeach the durability of Prolene.

c. Dr. Guelcher relies on unpublished Ethicon documents regarding Prolene sutures that do not support his opinion and would be highly prejudicial unless Ethicon can introduce evidence that the FDA approved Prolene sutures for use in the human body.

Dr. Guelcher also seeks to support his opinion that Prolene is subject to degradation and embrittlement by pointing to Ethicon's 1987 Prolene suture study, *see* Ex. AA, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.12831391–392, and its seven-year dog study of Prolene sutures, *see* Ex. BB, Seven Year Data for Ten Year Prolene Study (Oct. 15, 1992),

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"elevated temperatures" means "[t]emperatures above 100 C," and that normal human body temperature is 37 degrees Celsius. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 61:3–16. Dr. Guelcher also admitted that he could not quantify the alleged *in vivo* autoxidation of Prolene, and explained that he "do[es]n't think it's relevant" to his opinions. *Id.* at 61:22–62:15. Dr. Guelcher should not be permitted to opine on this issue at trial because he cannot explain the relevance of autoxidation of polypropylene outside the human body at temperatures far exceeding *in vivo* conditions.

ETH.MESH.07690752–756. Significantly, these tests did not show any adverse effects on the sutures due to degradation. *See* Ex. CC, Barbolt 1/8/14 Dep. Tr. 560–562.

These internal Ethicon documents do not support Dr. Guelcher's opinions in this case. Dr. Guelcher cannot rely on the 1987 suture test because it did not report a change in molecular weight in the sutures, which Dr. Howard Jordi—one of Plaintiffs' experts—has acknowledged is necessary to prove degradation. *See* Ex. DD, Jordi 10/30/13 Dep. Tr. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene). Nor did the test make any findings with respect to elongation or tensile strength. With respect to the seven-year dog study, Dr. Guelcher has admitted at trial that there is no evidence of embrittlement, loss of mechanical properties, or loss of molecular weight in that study. *See* Ex. E, *Huskey* 8/25/2014 Trial Tr. 180:3–183:14.

In addition, Ethicon submits that Dr. Guelcher should not be permitted to testify that Prolene degrades based on his review of these internal Ethicon documents which assess Prolene polypropylene sutures, unless Ethicon can introduce evidence regarding the FDA approval and regulation of the Prolene polypropylene sutures. As the Court is aware, the FDA approved Prolene polypropylene sutures as an implantable medical device when it approved the Prolene polypropylene suture New Drug Application in 1969. *See, e.g.*, Mem. Supp. Mot. Partial Summ. Judg. Based on Preemption [ECF No. 129], *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301 (S.D. W. Va. Dec. 12, 2013), at 2–4. The FDA in 1988 approved labeling which said that the Prolene sutures were "not subject to degradation or weakening by the action of tissue enzymes." *Id*. From 1976 to 1990, the FDA regulated Prolene sutures as a Class III medical device subject to the Premarket Approval ("PMA") process. *See id.* at 4. In 1990, the FDA reclassified Prolene

and other polypropylene sutures as a Class II device, subject to less rigorous controls, based on the proven safety and effectiveness of polypropylene sutures. *See id.* at 4–5.

As the Court has recognized, the FDA's PMA review is much more rigorous than the 510(k) process, and design-defect claims for PMA-approved devices are typically preempted. *See, e.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014) (discussing differences between PMA and 510(k) processes and acknowledging that "tort claims regarding medical devices approved through the premarket approval process generally are preempted"). Thus, if the Plaintiffs were suing for alleged design defects in Prolene sutures, their claims would likely be preempted in light of the FDA's approval of these devices.

In prior cases in this MDL, the Court has consistently excluded evidence of FDA actions. Assuming the Court maintains that approach here, Ethicon will be unduly prejudiced by any testimony from Dr. Guelcher regarding or based on the alleged *in vivo* degradation of Prolene sutures. Otherwise, Dr. Guelcher would be free to testify that Prolene sutures degrade *in vivo*, but the Defendants would be unable to rebut this opinion with evidence that the FDA specifically approved Prolene for use in sutures and considered Prolene and other polypropylene sutures to be free from harmful degradation and safe and effective for use in the human body.

C. Dr. Guelcher is Not Qualified to Opine that Degradation Causes Complications *In Vivo*, and His Opinions Regarding Complications are Unreliable.

Dr. Guelcher seeks to opine that degradation causes "adverse events like pain, scarring and inflammation." *See* Ex. B, Guelcher Report at 16–19; *see also* Ex. D, Guelcher 3/23/16 Dep. Tr. 107:13–20. Not only does Dr. Guelcher lack the specialized knowledge, skill, experience, training, and education to opine as to complications allegedly caused by degradation, but his testimony demonstrates that his opinions lack any indicia of reliability. There simply is no scientific testing or other evidence to show that Prolene degrades in the human body in a way

that has clinical significance; absent clinical significance, any evidence about degradation is immaterial and unfairly prejudicial.

Dr. Guelcher is not a medical doctor. *See* Ex. C, Guelcher 12/18/14 Dep. Tr. 18:23–19:5. He has never conducted the differential diagnoses necessary to determine whether a patient's mesh caused clinical symptoms like pain, dyspareunia, or any other complications. *See, e.g., id* at 253:1–12; 253:20–254:5. Indeed, he admitted at deposition that he did not know what a differential diagnosis is. *Id.* at 201:2–12. Dr. Guelcher's lack of qualification to offer opinions regarding the clinical complications allegedly caused by degradation is, by itself, a sufficient basis for the Court to exclude his testimony on these issues. *See, e.g., Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) (excluding expert testimony that went "beyond the experts' qualifications").

In addition to his lack of qualifications to opine on clinical complications, Dr. Guelcher has admitted that he does not have the data to correlate any specific complication to the degradation of generic polypropylene, much less the Prolene at issue here. *See* Ex. EE, *Cardenas* 8/18/14 Trial Tr. 518:13–24. In fact, Dr. Guelcher testified that the "*clinical implications of [oxidative degradation] are unknown.*" Ex. D, Guelcher 3/23/16 Dep. Tr. 97:11–14 (emphasis added).

Nor can Dr. Guelcher base his opinions regarding complications on scientific or medical literature. As an initial matter, for the reasons discussed above, the studies on which Dr. Guelcher relies fail to support his opinions regarding complications.

In addition, Dr. Guelcher's own writings demonstrate that these opinions are unreliable. In a study he co-authored with Dr. Vladimir Iakovlev—another expert for plaintiffs in pelvic mesh litigation—Dr. Guelcher acknowledged that the "exact mechanisms of these late

complications are yet to be understood," and the role of degradation "need[s] to be studied more extensively for [its] role[] in the development of these complications." *See* Ex. R, V. Iakovlev, *et al.*, *Degradation of Polypropylene* In Vivo*: A Microscopic Analysis of Meshes Explanted From Patients*, J. Biomed. Mater. Res. Part B, at 10–11 (2015). Thus, while Dr. Guelcher seeks to inform the jury that degradation of the Prolene in Ethicon mesh products causes complications *in vivo*, he refuses to make such a causal connection in his out-of-court writings. *See Mathison*, 2015 WL 2124991 at *10 (excluding opinion of expert who applied lower standard to litigation opinions than he did to his own peer-reviewed literature).

The Court should preclude Dr. Guelcher from testifying about complications allegedly caused by degradation because he is not qualified to offer such opinions, his testimony demonstrates that his opinions are not based in scientific evidence, and his own publications demonstrate that the opinions he seeks to offer at trial are not consistent with his work outside of litigation. *See Kumho*, 526 U.S. at 152 (explaining that an expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."); *see also Johnson & Johnson v. Batiste*, 2015 6751063, at *6, *9 (Tex. App.—Dallas Nov. 5, 2015, pet. pending) (concluding that evidence of degradation is legally insufficient where plaintiffs' experts could not identify testing establishing the clinical consequences of any alleged degradation).[13]

[13] The disparity between Dr. Guelcher's opinions regarding Prolene in litigation and his out-of-court conduct is highlighted by his testimony regarding his efforts to discuss the alleged risks posed by Prolene with doctors at Vanderbilt, the university at which he is employed. Specifically, Dr. Guelcher admitted that he has never "discussed [his] opinions" regarding the safety of Prolene mesh with any doctor at Vanderbilt. *See* Ex. D, Guelcher 3/23/16 Dep. Tr. 18:6–14. Indeed, although he testified that he "had some email correspondence with a Vanderbilt OB/GYN, he stated that he has never told any doctor at Vanderbilt that he believes Prolene mesh degrades, because he "ha[s]n't had the opportunity." *Id.* at 18:6–21.

III. Dr. Guelcher's Opinions Concerning Ethicon's Purported Knowledge, State of Mind, and Corporate Conduct Do Not Assist the Trier of Fact.

Throughout his Report, Dr. Guelcher opines as to Ethicon's alleged knowledge regarding a variety of topics. For instance, he opines that the "effects of oxidation on Prolene's stability were known to Ethicon prior to launching the TVT device, but the company did not consider the risks associated with polypropylene oxidation . . . ." *See* Ex. B, Guelcher Report at 3. He claims that "Ethicon was sufficiently aware of Prolene surface cracking to form a committee to investigate the mechanism of cracking," (*id.* at 13), and that "Ethicon has also been made aware of the specific risks inherent to using PP in an implantable medical device through the Material Safety Data Sheet . . . ." (*id.* at 15–16). He states that "Ethicon documents indicate that the company was aware of the Costello article in 2007, but never considered the effect of oxidation during its design or product lifecycle." *Id.* at 19. In support of these opinions, Dr. Guelcher spends several pages of his Report presenting his interpretation of a series of Ethicon's internal documents. *See, e.g., id.* at 13–17, 19.

The Court should preclude Dr. Guelcher from offering opinions concerning Ethicon's internal documents, corporate knowledge and conduct. This Court has repeatedly held that a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013).

Finally, Dr. Guelcher is not qualified to opine as to Ethicon's corporate knowledge and conduct. Dr. Guelcher is a chemical engineer. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization

that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at 9 (E.D. Pa. June 20, 2000). Dr. Guelcher is thus unqualified to offer any opinions concerning Ethicon's corporate conduct.

For all of the reasons set forth above, the Court should preclude Dr. Guelcher from offering a narrative summary of Ethicon's documents or opinions concerning Ethicon's purported knowledge, state of mind, and corporate conduct.

IV. Conclusion

For these reasons, Ethicon respectfully requests that the Court grant its Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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